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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/628,920	07/29/2003	Lee R. Bolduc	HRT-0303CON	8124

27777 7590 03/17/2009

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ART UNIT	PAPER NUMBER
3734	
MAIL DATE	DELIVERY MODE
03/17/2009	PAPER

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte LEE R. BOLDUC,
HANSON S. GIFFORD III, and JAMES I. FANN

Appeal 2009-1255
Application 10/628,920
Technology Center 3700

Decided:[1] March 17, 2009

Before DONALD E. ADAMS, ERIC GRIMES, and
JEFFREY N. FREDMAN, *Administrative Patent Judges*.

ADAMS, *Administrative Patent Judge*.

DECISION ON APPEAL

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[1] The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, begins to run from the decided date shown on this page of the decision. The time period does not run from the Mail Date (paper delivery) or Notification Date (electronic delivery).

This appeal under 35 U.S.C. § 134 involves claims 58-69. The Examiner has indicated that claims 70-72, the only other claims pending in this application, are allowable (*see* Final Rejection, mailed March 29, 2007, 3). We have jurisdiction under 35 U.S.C. § 6(b).

STATEMENT OF THE CASE

Claims are directed to a method of forming an anastomosis by placing a lumen of a graft vessel in fluid communication with a lumen of a target vessel through an opening in a wall of the target vessel. Claim 58 is illustrative:

58. A method of forming an anastomosis by placing a lumen of a graft vessel in fluid communication with a lumen of a target vessel through an opening in a wall of the target vessel, comprising the steps of:

providing a plurality of clips, the clips being made of superelastic material, each of the plurality of clips each having a first end and a second end, a first configuration, where the first end and second end are spaced apart so as to be able to receive therebetween a portion of the graft vessel and a portion of a target vessel tissue proximate the opening in the wall of the target vessel, and a second configuration, where the portion of the graft vessel and the portion of the target vessel are approximated;

positioning the first end of each of the plurality of clips through the opening in the target vessel;

passing the first end of each of the plurality of clips through an inner wall of the target vessel while the clips are in the first configuration;

passing at least a portion of each of the plurality of clips through the graft vessel and

permitting each of the plurality of clips to assume the second position to approximate the graft vessel and the target vessel.

The Examiner relies on the following evidence:

Gwathmey et al.	US 4,809,695	Mar. 7, 1989
Yoon	US 5,330,503	Jul. 19, 1994

The rejection presented by the Examiner is as follows:

Claims 58-69 stand rejected under 35 U.S.C § 103(a) as unpatentable over the combination of Gwathmey and Yoon.

We reverse.

ISSUE

Does the combination of Gwathmey and Yoon teach every element of the claimed invention?

FINDINGS OF FACT

FF 1. The Examiner finds that Gwathmey teaches

> A method of forming an anastomosis by placing a lumen of a graft vessel in fluid communication with a lumen of a target vessel through an opening in a wall of the target vessel including the steps of providing a plurality of clips (col. 7, line 15-16) having a first end and a second end (ref. 120, Fig. 4), and each clip having a first configuration (see Fig. 18) and a second configuration (see Fig. 19); passing the first end of each of the plurality of clips through an outer wall of the graft vessel (see Fig. 19; the clips must go through part of the outer wall of the graft vessel in order to form the anastomosis); positioning the first end of the clips through the opening and inner wall of the target vessel (Fig. 18; col. 7, line 32-3[9 ("the surgeon can manipulate the cartridge **14** to dig the staple-leg tips . . . on one side of the cartridge into tissue on one side of the flange **118** while the cartridge is rotated . . . to bring the staple-leg pointed tips on the other side of the cartridge to the other side of the tissue flange so that the staples are in the position shown in FIG. 18 with respect to the tissue flange **118**")]; when the

surgeon makes the flange, the staple goes through the interior of the target vessel wall); passing at least a portion of the clip through the graft vessel (col. 7, lines 34-39); permitting each of the clips to assume a second position to approximate the two vessels (see Fig. 19; col. 7, line 5-61).

(Ans. 3.)

FF 2. For clarity we reproduce Gwathmey's figures 18 and 19 below:

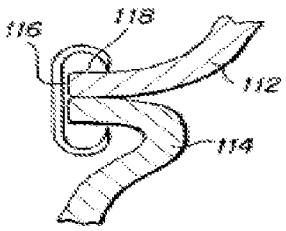

FIG. 18

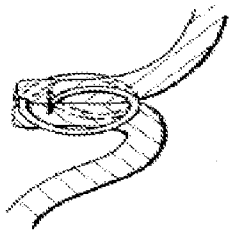

FIG. 19

FIG. **18** is a side sectional view of two pieces of tissue having their edges everted to form a flange which is inserted into the mouth of a staple of the assembly of FIG. **1** before the staple has been closed by the cartridge and pliers-like clamping tool thereof;

FIG. **19** is a view similar to FIG. **18** in which the staple has been closed [by] the cartrid[g]e and pliers-like tool;

(Gwathmey, col. 4, ll. 28-34.)

FF 3. The Examiner finds that Gwathmey is "silent on the material of the clip but do disclose that the clip must have the capability of being able to be bent into the looped configuration" (Ans. 4; *Cf.* Gwathmey, col. 6, ll. 39-42 ("In a preferred embodiment . . . [t]he staples **16** are constructed of 316L stainless steel and have diameters ranging from 0.004 inches to 0.1 inch, depending on their uses")).

FF 4. Appellants' only disclosure of a superelastic material is that the clip is preferably "made of a superelastic shape memory alloy such as Nitinol"

(Spec. 24: 16-17). The Examiner defines a "superelastic material . . . as a material that is capable of changing from one configuration to another when a force that holds the clip in the first position is removed, as disclosed in the present application [at page 23, lines 16-17]" (Ans. 4).

FF 5. The Examiner finds that Yoon discloses a suturing device that "contracts after it is inserted into tissue, returning to its pre-suturing shape (col. 8, lines 59-62). Based on the definition being used, the suture material of Yoon is superelastic" (Ans. 4).

PRINCIPLES OF LAW

"In proceedings before the Patent and Trademark Office, the Examiner bears the burden of establishing a prima facie case of obviousness based upon the prior art." *In re Fritch*, 972 F.2d 1260, 1265 (Fed. Cir. 1992). On appeal to this Board, Appellants must show that the Examiner has not sustained the required burden. *See* (1) *Ex parte Yamaguchi*, http://www.uspto.gov/web/offices/dcom/bpai/ prec/fd074412.pdf, slip op. at 5 and 23 (BPAI Aug. 29, 2008) (precedential); (2) *Ex parte Fu*, http://www.uspto.gov/web/offices/ dcom/bpai/prec/fd080601.pdf, slip op. at 5 and 20 (BPAI Mar. 31, 2008) (precedential); (3) *Ex parte Catan*, http://www.uspto.gov/web/ offices/dcom/bpai/prec/fd070820.pdf, slip op. at 3 and 21 (BPAI Jul. 3, 2007) (precedential), and (4) *Ex parte Smith*, http://www.uspto.gov/web/offices/dcom/bpai/prec/fd071925.pdf, slip op. at 4, 9 and 23 (BPAI Jun. 25, 2007).

"The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results."

KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, ___, 127 S. Ct. 1727, 1739 (2007).

> When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103.

Id. at 1742. It is proper to "take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *KSR*, 127 S. Ct. at 1741. *See also id.* at 1742 ("A person of ordinary skill is also a person of ordinary creativity, not an automaton."). "In determining whether obviousness is established by combining the teachings of the prior art, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art." *In re GPAC Inc.*, 57 F.3d 1573, 1581 (Fed. Cir. 1995) (internal quotations omitted).

ANALYSIS

Based on the foregoing evidence (FF 1-5), the Examiner concludes that

> It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified Gwathmey et al. with a clip made out of superelastic shape memory material, as taught by Yoon, in order to allow the clip to have the flexibility to be formed into a looped/crossed-over configuration as described in Gwathmey et al. and to have the capability of moving to a second configuration once inserted into tissue and once the insertion device has been removed.

(Ans. 4.) Appellants contend that the combination of Gwathmey and Yoon fails to "set forth each and every element of claim 58" (App. Br. 4). All other claims on appeal depend directly or indirectly from claim 58. Specifically, Appellants contend, *inter alia*, that "the first ends of each of the plurality of clips [are not] passed through an inner wall of the target vessel ***while the clips are in the first configuration***" (App. Br. 4). We agree.

Gwathmey's FIG. 18 illustrates how the everted edges of the target and the graft vessel are positioned in a staple (e.g., clip) in a first position (FF 2). As illustrated in Gwathmey's FIG. 18, in an everted condition, the inside wall of the graft vessel is in contact with the inside wall of the target vessel. Therefore, as illustrated in Gwathmey's FIG. 18, at best, a staple in a first configuration may engage the outer wall of the target and graft vessels. The staple does not, however, pass through an inner wall of the target vessel while the clip is in the first configuration as is required by Appellants' claimed invention. To the contrary, the staple does not pass through an inner wall of the target vessel until the staple is no longer in a first configuration (*see, e.g.,* Gwathmey's FIG. 19).

For the foregoing reasons, we find that the preponderance of the evidence on this record supports Appellants' contention.

CONCLUSION OF LAW

For the foregoing reasons, the preponderance of evidence on this record fails to support a conclusion that the combination of Gwathmey and Yoon teaches every element of the claimed invention.

The rejection of claims 58-69 under 35 U.S.C § 103(a) as unpatentable over the combination of Gwathmey and Yoon is reversed.

REVERSED

cdc

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